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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,165	09/11/2003	Ravinder S. Dhallan	543312000420	7501

25226 7590 10/12/2006  
MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER
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WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/661,165		DHALLAN, RAVINDER S.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ethan Whisenant, Ph.D.		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-12,14-16,18-102,132-146,148-155 and 181-208 is/are pending in the application.  
     4a) Of the above claim(s) 153-155 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,8-12,14-16,18-83,87-102,132-146,148-152 and 181-208 is/are allowed.
- 6) ☒ Claim(s) 84-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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## **FINAL ACTION**

1. The applicant's response (filed 14 JUL 06) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-6, 8-12, 14-16, 18-102, 132-146, 148-155 and 181-208** is/are pending with Claims 153-155 withdrawn from consideration. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

## **INTERVIEW SUMMARY**

2. The applicant described the invention and pointed to the distinguishing limitation(s) in each of the independent claims (i.e. Claims 1, 58, 84, 85, 87 and 152). They also pointed out that essentially the same arguments discussed during the interview had been presented in the amendment filed 14 JUL 06. As regards Claim 1 and 84-85, the applicant pointed to the limitation which requires that the fetal template DNA analyzed come from a pregnant female and is present in a mixture of maternal DNA and fetal DNA. As regards Claims 58, 87 and 152 the applicant pointed out they EDTA could not be defined as a cell lysis inhibitor but rather was simply an anticoagulant. They also stressed that Claims 58, 87 and 152 was directed towards the isolation and analyse free fetal DNA [ i.e. extracellular DNA derived from the fetus and present in a sample taken from a pregnant females (e.g.blood)].

### 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

### CLAIM REJECTIONS UNDER 35 USC § 103

4. **Claim(s) 84-86** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. [US 2003/0082576 (MAY 2003)] or Shapero et al. [Genome Research 11 :1926-1934 (2001)] in view of Lagona et al. [Human Genetics 102 : 687-690 (1998)].

Jones et al. and Shapero et al. teach a method for determining the sequence of a locus of interest from template DNA comprising all of the limitations recited in Claim 84, except these authors do not teach that the template DNA come from a pregnant female and that the template DNA comprise a mixture of fetal DNA and maternal DNA. However, as evidenced by at least Lagona et al. it was well known in the art prior to the instant invention to obtain and analyze template DNA comprising a mixture of fetal DNA and maternal DNA. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the DNA samples taught by Lagona et al. for those utilized by Jones et al. or Shapero et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose.

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Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

#### **RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS**

5. Applicant's arguments with respect to the claimed invention have been fully and carefully but are moot in view of the new grounds of rejection. As regards the applicant contention that the claim limitation(s) in Claims 84 and 85 which requires analyzing template DNA wherein the template DNA comprises a mixture of fetal DNA and maternal DNA distinguishes over the prior art, the examiner notes that as evidenced by at least Lagona et al. [Human Genetics 102 : 687-690 (1998)] it was well known prior to the instant invention to analyze a DNA template by amplification means wherein the template DNA comprises a mixture of fetal DNA and maternal DNA.

#### **REASON FOR ALLOWANCE**

6. Independent **Claim(s) 1 , 58, 87 and 152** is/are deemed to be allowable in light of the applicant's amendment filed 14 JUL 06 and the persuasive argument(s) therein.

#### **CONCLUSION**

7. **Claim(s) 1-6, 8-12, 14-16, 18-83, 87-102, 132-146, 148-155 and 181-208** is/are allowable while Claim(s) 84-86 is/are rejected and/or objected to for the reason(s) set forth above.

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8. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**ETHAN WHISENANT**  
**PRIMARY EXAMINER**

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